DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-151/S-004

Berlex Laboratories, Inc.
Attention: Ms. Maria C. Garrigan
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Garrigan:

Please refer to your supplemental new drug application dated March 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betapace AF (sotalol hydrochloride) 80, 120, and 160 mg Tablets.

We acknowledge receipt of your submissions dated May 6 and November 14, 2002 and March 5, 2003.

Your submission of November 14, 2002 constituted a complete response to our July 11, 2002 action letter.

This supplemental new drug application provides for a new 100 mg strength tablet.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 14, 2002.

At the time of the next printing, please change the storage statement from:

> Store at 25° C (77° F) with excursions permitted between 15°-30°C (59°-86° F). [See USP Controlled Room Temperature]
>
> To:
>
> Store at 25° C (77° F); excursions permitted to 15°-30° C (59°-86° F) [See USP Controlled Room Temperature].
> Or if space does not permit the previous on the immediate container labels:
> Store at 25° C (77° F); excursions permitted to 15°-30 C (59°-86° F) [see insert].

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

> Division of Drug Marketing, Advertising, and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

> MEDWATCH, HF-2
> FDA
> 5600 Fishers Lane
> Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Melissa Robb
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge
3/14/03 02:06:16 PM
For Douglas Throckmorton